Remarks

Amendments to the Claims

The claims have been amended to replace the word "system" with "composition". Support is found at page 5, line 28.

The reference to "naked DNA" (for which the undersigned could not find explicit support in the specification, although implicit support is present), has been replaced with "gene", defined at page 13, lines 33-35.

The claims now recite that the polymeric matrix is in the form of a film, coating, gel, slab or stent. Explicit support is found at page 5, lines 20-21.

The limitation of claim 9 was incorporated into claim 3, and the claim was amended to recite that the gene encoded a protein. Support is found at page 14, lines 7-8.

Effective Priority Date

As discussed below, the effective filing date of this application is March 15, 1994, since this application is a continuation or divisional of all applications claiming priority to the application filed March 14, 1994.

Rejections under 35 U.S.C. 112

Claims 3-18 were rejected under 35 U.S.C. 112, as lacking written support. This rejection is respectfully traversed.

Explicit written support for the polymeric matrix in the form of a coating, gel, implant, film or stent is found at page 5, lines 20-21. Additional support is found at page 13, lines 13-16.

The phrase "system", while believed to be supported by the specification, has been replaced by the word "composition", which is explicitly disclosed at least at page 5, line 28.

The rejection of claim 18 is not understood. The specification clearly recites incorporation of at least 20 micrograms of DNA, as well as a drug loading of between 0.01 and 90%, which would be at least 20 micrograms for a device such as a stent. However, the claim has been cancelled so the rejection is now moot.

Claim 17 is clear and enabled. It is common in the polymeric drug delivery field to shape a polymer after implantation, usually by implanting the polymer at the time of or shortly after initiating polymerization. For example, if the examiner has used epoxy, then the examiner is aware that you mix two materials, one including the catalyst which initiates the reaction, but that the material does not harden until crosslinking is complete. The same can be achieved by adding calcium ions to alginate, which over a period of several minutes hardens as ionic crosslinks form between the alginate molecules. The latter is the system described in Table I, page 13. The system referenced on page 13, line 18, is a diacrylated-poly(lactide-co-glycolide)-PEG polymer that is FDA approved, marketed now by Genzyme, and polymerized in situ by brief exposure to ultraviolet light at low levels (seconds of exposure, which does not cause DNA damage, which was established by Genzyme and its predecessor Focal to the satisfaction of the FDA, since although the polymer did not contain DNA, it was applied to living cells, which do contain DNA). The statement at page 13 that this process can be carried out *in vitro* as well as *in vivo* fully supports polymerization prior to or after implantation, particularly in view of the foregoing discussion and disclosure in the specification as filed.

Rejections under 35 U.S.C. 102

Claims 3-7, 9-13, and 15-17 were rejected under 35 U.S.C. 102(e) over U.S. Patent No. 5,639,473 to Grinstaff, et al., or U.S. Patent No. 5,763,416 to Bonadio, et al., U.S. Patent No. 5,820,883 to Tice, et al. These rejections are respectfully traversed.

Grinstaff and Bonadio are not available as prior art

As noted above, the present application is fully entitled to a filing date of March 15, 1994.

Grinstaff, et al., claims priority as a continuation to a filing date of February 22, 1994, and as a continuation in part to a filing date of February 22, 1993 and March 26, 1993. Grinstaff was published after the priority date of this application, March 15, 1994.

Bonadio, et al., issued on an application filed February 18, 1994, and was published after the priority date of this application, March 15, 1994.

Attached is a Declaration under 37 C.F.R. 1.131 which provides evidence that the applicants had conceived and reduced to practice the claimed subject matter prior to February 22, 1993. The executed declaration will be submitted shortly. This declaration removes Grinstaff and Bonadio as prior art.

Tice does not disclose films, gels, coatings, slabs or stents

Tice does not disclose films, gels, coatings, slabs or stents. Tice discloses only microparticles, either microcapsules or microspheres. See col. 4, lines 56-57, col. 8, lines 7-19; all of the examples. Indeed, the point of the patent is that microcapsules are phagocytized and therefore useful as a delivery system. Since the claims are drawn specifically to films, gels, coatings, implants or stents, Tice does not disclose the claimed

subject matter. 35 U.S.C. 102 requires the reference to disclose each claimed element. Tice does not do so.

Rejections under 35 U.S.C. 103

Claims 3-7, 9-13, and 15-17 were rejected under 35 U.S.C. 103 as obvious over U.S. Patent No. 5,770,580 to Ledley, et al., in combination with Bonadio or Grinstaff. This rejection is respectfully traversed.

As noted above, Bonadio and Grinstaff are not available as prior art.

Ledley appears to be correctly characterized by the examiner. However, there is no teaching that would have led one of skill in the art to have a reasonable expectation that the DNA could be encapsulated into a polymeric matrix and delivered. Indeed, at the time this application was filed, the general consensus was that this was not possible. Since neither Bonadio nor Grinstaff is available as prior art, even if there were some disclosure leading one to combine Ledley with Bonadio or Grinstaff, which there is not, Ledley cannot make obvious the claimed subject matter.

Double Patenting

Claims 3-18 were rejected under the doctrine of obviousness type double patenting over claims 1 and 2 of U.S. Patent No. 6,620,617 or claims 1-8 of U.S. Patent No. 6,475,779 or claims 1-14 of U.S. Patent No. 6,262,034. These rejections are respectfully traversed.

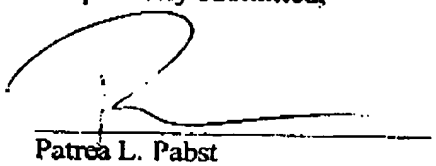
The rejection seems to be based on the premise that because the claims in these patents are all related to polymeric microspheres that contain DNA, that such microspheres make obvious polymeric slabs, films, coatings, gels, or stents. However, the examiner has provide no argument and no secondary references why one of skill in

the art would look at claims to microparticles, or methods of manufacture or use thereof, and be led to substitute slabs, films, coatings, gels or stents, with an expectation of success.

This is improper and legally unsupportable. An obviousness type double patenting rejection must be supported in the same way as an obviousness rejection under 35 U.S.C. 103, with the difference that one can only look to the claims, not to the specification. The examiner has failed to do so. No where is there anything in the claims of the issued patents that would lead one to the claims in this application. It is not enough that the applications claim priority to each other or share common features (polymer, gene). There must be motivation to modify as applicants have done in the claims in this application.

Allowance of claims 3-17, as amended, is earnestly solicited.

Respectfully submitted,



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